



PATENT APPLICATION

THE U.S. PATENT AND TRADEMARK OFFICE

April 20, 2004

Applicants: Junzo SUNAMOTO et al

For: COSMETIC PRODUCT CONTAINING
POLYSACCHARIDE-STEROL DERIVATIVE

Serial No.: 09/936 953 Group: 1617

Confirmation No.: 4435

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International Application No.: PCT/JP00/02044

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Atty. Docket No.: Yanagihara Case 62

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF ON APPEAL

Sir:

This is an appeal from the decision of the Examiner dated July 22, 2003 finally rejecting Claims 1, 4, 5 and 7-9.

REAL PARTY IN INTEREST

NOF Corporation and Junzo SUNAMOTO are the assignees of the present application and the real party in interest.

RELATED APPEALS AND INTERFERENCES

The present application has no related appeals and interferences.

STATUS OF CLAIMS

Claims 1, 4, 5 and 7-9 are pending and are the claims on appeal. Claims 2, 3 and 6 have been canceled.

STATUS OF AMENDMENTS

The Amendment After Final Rejection dated January 22, 2004 has not been entered by the Examiner.

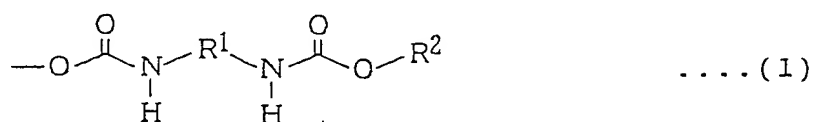
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SUMMARY OF INVENTION

Appellants' invention, as defined by independent Claim 1, is directed to a cosmetic product containing a polysaccharide-sterol derivative which comprises cosmetic components and a pullulan-cholesterol derivative. The hydroxyl groups of monosaccharide units constituting the pullulan of the pullulan-cholesterol derivative are substituted, in a proportion of 0.01-20 groups per 100 monosaccharide units, by a radical represented by the formula (1)



in which R¹ denotes a hydrocarbon group containing 1-10 carbon atoms and R² represents a cholesteryl group (specification page 6, lines 1-3 and specification page 5, lines 11-20).

Claim 4 limits Claim 1 in requiring that the proportion of cholesteryl groups introduced by substitution for the hydroxyl groups of the monosaccharide units of the pullulan is 0.05-15 groups per 100 monosaccharide units (specification page 5, lines 21-24).

Claim 5 limits Claim 1 in requiring that the proportion of cholesteryl groups introduced by substitution for the hydroxyl groups of the monosaccharide units of the pullulan is 0.1-10 groups per 100 monosaccharide units (specification page 5, lines 25-28).

Claim 7 limits Claim 1 in requiring that the content of the pullulan-cholesterol derivative is in the range from 0.001-50%, based on the total weight of the cosmetic product (specification page 6, lines 4-8).

Claim 8 limits Claim 1 in requiring that the cosmetic product is a skin care cosmetic, make-up cosmetic or hair conditioning cosmetic (specification page 6, lines 9-12).

Claim 9 limits Claim 1 in requiring that the cosmetic product is an emulsion, a beauty wash, a rouge, a manicure product or a hair lotion (specification page 6, lines 13-16).

ISSUES

The first issue presented for review is whether Claims 1 and 7 are unpatentable under 35 USC 112, second paragraph, as being indefinite. The second issue presented for review is whether Claims 1, 4, 5, 7 and 9 are anticipated under 35 USC 102(b) over Yamaguchi et al. The third issue presented for review is whether Claim 8 is unpatentable under 35 USC 103(a) over Yamaguchi et al and further in view of Kondo et al and Force et al.

GROUPING OF CLAIMS

Claims 1, 4, 5 and 7-9 all stand or fall together.

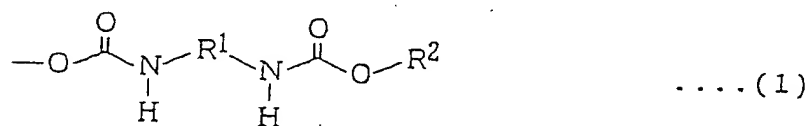
ARGUMENT

Claims 1 and 7 have been rejected under 35 USC 112, second paragraph, as being vague and indefinite for containing the term "pullulan-cholesterol derivative". The Examiner states that it is not readily apparent what, chemically, is encompassed by the term "derivative" and that the word "derivative" encompasses an incredible number of chemical modifications. However, Appellants wish to point out that the structure of the claimed derivative is clearly specified in Claim 1. That is, the "wherein" clause of Claim 1 specifies that the hydroxyl groups of monosaccharide units constituting the pullulan of the pullulan-cholesterol derivative are substituted, in a proportion of 0.01-20 groups per 100 monosaccharide units, by a radical represented by formula (1). As such, Appellants respectfully submit that the pullulan-cholesterol derivative of Claims 1 and 7 are clearly specified. Appellants posit that the Examiner has made a "knee-jerk" rejection under 35 USC 112, second paragraph, for merely using the term "derivative". While in some

circumstances, the rejection of a claim for the use of the term "derivative" under 35 USC 112, second paragraph, as being vague and indefinite is appropriate, in the present situation, the structure of the derivative is clearly pointed out. Therefore, this rejection clearly is in error and should be overturned.

The presently claimed invention is directed to a cosmetic product having a high moisture-retaining and film-forming ability, lamella formation facilitation, superior stabilization and low oily feel due to the incorporation of the inventive pullulan-cholesterol derivative. The properties of the cosmetic composition of the present invention enables it to be used in improving the conditions of the hair and skin caused by drying, such as rough skin and reduced luster of the hair, and provides moisturization of the skin and hair by retaining sufficient moisture therein while giving the hair and skin a superior touch and feel.

In the present invention, the pullulan-cholesterol derivative is formed by substituting the hydroxyl groups of monosaccharide units constituting the pullulan of the pullulan-cholesterol derivative, in a proportion of 0.01-20 groups per 100 monosaccharide units, by a radical represented by the formula (1)



in which R^1 denotes a hydrocarbon group containing 1-10 carbon atoms and R^2 represents a cholesteryl group. It is respectfully submitted that the presently claimed invention is patentably distinguishable over the prior art cited by the Examiner.

Yamaguchi et al, EP 0 370 810, discloses a fatty emulsion stabilized by a polysaccharide derivative which can be used in

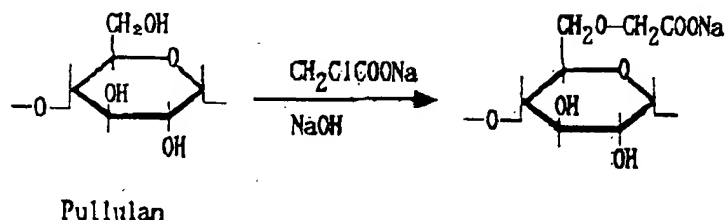
medicine, food and the like, and is disclosed in this reference as being a carrier which can embed fat-soluble substances in large quantities. On page 2, lines 49-52, Yamaguchi et al discloses that the hydroxyl groups of carbons situated in 6- or 3- positions of the sugar skeleton are substituted by $-OCH_2CONHCH_2CH_2NHR$ wherein R is H or a cholesteryloxycarbonyl group at a proportion of 0.5-3 per 100 sugar units.

Appellants pointed out to the Examiner in the Response dated May 30, 2003 that the spacer through which the pullulan and the cholesterol were bonded in Yamaguchi et al was different from that of the present invention. That is, the present invention requires that the spacer for bonding pullulan and cholesterol have the structure $-OCONHR^1NHCOO-R^2$, in which R^1 is a hydrocarbon group and R^2 is a cholesteryl group. In response to Appellants' arguments that the structure of the spacers of Yamaguchi et al and the spacer of the present invention being different, the Examiner states in the final rejection that "based on the Examples of Yamaguchi, the $-OCH_2$ group in the first described formula above is actually a $-CH_2O-$ group, which is the methoxy group of the pullulan." The Examiner appears to be disregarding the specific teachings of Yamaguchi et al and rewriting the disclosure thereof in a manner to provide support for her position in rejecting the present claims.

In order to further substantiate Appellants' position that the substituent shown in Yamaguchi et al is different from the substituent required in the present claims, Appellants outline below the reaction scheme used in Synthesis Example 1 to obtain the cholesterol-modified pullulan disclosed there.

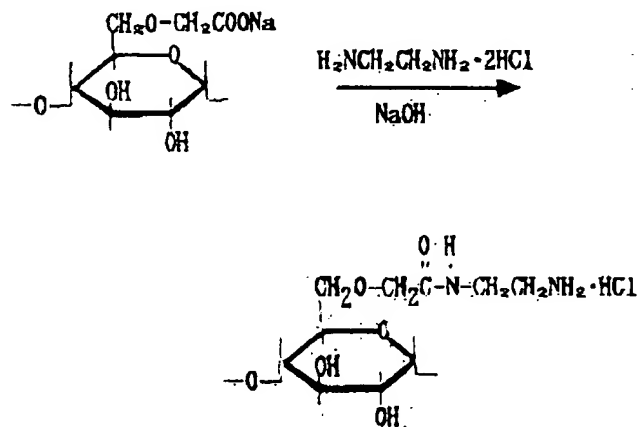
Carboxymethylated pullulan is synthesized in Yamaguchi et al by reacting pullulan with sodium monochloro acetate in the presence of sodium hydroxide. This reaction is shown below in Reaction Scheme 1

Reaction scheme 1



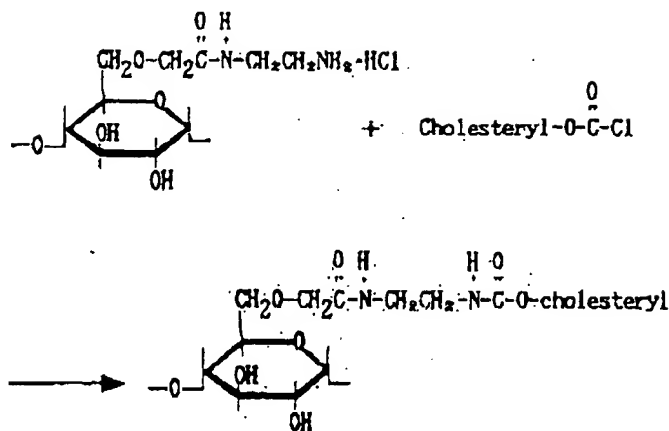
A carboxymethylated pullulan is then reacted with ethylene diamine dihydrochloride in the presence of sodium hydroxide and hydrochloric acid to give N-(2-aminoethyl)carbamoyl methylated pullulan as shown in reaction scheme 2.

Reaction scheme 2



N-[2-(cholesteryloxycarbonylamino)ethyl]carbamoyl-methylated pullulan is then synthesized by reacting N-(2-aminoethyl)carbamoyl methylated pullulan with cholesteryl chloroformate as shown in reaction 3 below where the chloride radical of cholesteryl chloroformate is replaced by an amino group to form an amido coupling.

Reaction scheme 3



As shown above, clearly in contrast with the Examiner's position, the substituent of Yamaguchi et al consists of "-OCH₂CONHCH₂CH₂NHR" in contrast to the "-OCONHR1NHCOO-R2", in which R1 is a hydrocarbon group and R2 is cholesteryl group as required by the present claims. Therefore, the Yamaguchi et al reference clearly does not anticipate the currently presented claims under 35 USC 102 and, in fact, does not even present a showing of structural obviousness as there is no art recognized equivalents between a methoxy group and a carboxy group in the contexts of the references or the present invention.

Kondo et al and Force et al have been cited by the Examiner as secondary references for teaching the use of oils, particularly perilla oil and soybean oil, in cosmetic compositions and, as such, makes it obvious to add either of these oils to the composition disclosed in Yamaguchi et al. However, the Yamaguchi et al reference is concerned with stabilizing a fatty emulsion which is used in medicine, food and the like. The fatty emulsions disclosed in this reference may use oils and fats, such as fish oil, α -linolenic acid and

other easily oxidizable and expensive fats. This suggests that the fatty emulsion is intended to be used in nutrient infusion to be administered to the body via a blood vessel. Page 6, lines 1-4, of this reference supports this position in that it teaches that the emulsion should have a particle size of about 0.3 microns to stabilize the emulsion.

The Force et al reference is concerned with the formation of skin and hair care cosmetic preparations. Given the divergent art to which Force et al and Yamaguchi et al are directed, one of ordinary skill in the art clearly would attempt to combine these references. While the Kondo et al reference is directed to a medicine, it is directed to an external medicine to be applied to the skin to prevent skin inflammation and drying. Once again, given that the Yamaguchi et al reference is concerned with an internal medicine and the Kondo et al reference is concerned with an external medicine, Appellants respectfully submit that one of ordinary skill in the art would not attempt to add the perilla oil of Kondo et al to the internal medicine or food of Yamaguchi et al. More importantly, there is no motivation contained in either one of the secondary references to modify the substituent of Yamaguchi et al in a manner that would yield the presently claimed invention. As such, it is respectfully submitted that the presently claimed invention clearly is patentably distinguishable over Yamaguchi et al in combination with either Force et al or Kondo et al.

Even though the Examiner has not made a showing of prima facie obviousness under 35 USC 103 with respect to the currently presented claims, Appellants respectfully submit that the objective evidence of record is sufficient to overcome any proper prima facie obviousness rejection under 35 USC 103. That is, as illustrated by the results of the transcription test for oil/water type milky lotions shown in Table 1 of the present specification, the test for improving artificial rough skin by oil/water type milky lotions shown in Table 2, the practical application test with oil/water type

milky lotions shown in Table 3, the test for testing the effect of a hair lotion disclosed in Table 5, the transcription test for a liquid lip rouge shown in Table 6 and the test for assessing a colored manicure liquid disclosed in Table 7, as compared with the results of the Comparative Examples, the presently claimed compositions clearly have unobviously superior properties. Nothing in the references cited by the Examiner would suggest such an effect and, as such, it is respectfully submitted that the patentability of the presently claimed invention has been established.

CONCLUSION

For the reasons advanced above, it is respectfully submitted that the Examiner's rejection of Claims 1, 4, 5 and 7-9 are in error and should be reversed. Favorable consideration is respectfully solicited.

Respectfully submitted,

IN TRIPLICATE


Terryence F. Chapman

TFC/smd

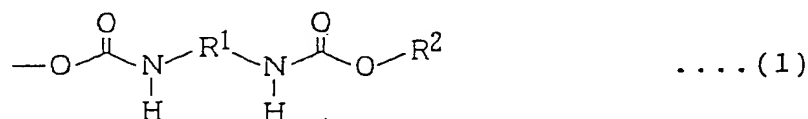
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Encl: Appendix
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APPENDIX

1. A cosmetic product comprising cosmetic components and a pullulan-cholesterol derivative, wherein the hydroxyl groups of mono-saccharide units constituting the pullulan of the pullulan-cholesterol derivative are substituted, in a proportion of 0.01 to 20 groups per 100 monosaccharide units, by a radical represented by the formula (1)



in which R^1 denotes a hydrocarbon group containing 1-10 carbon atoms and R^2 represents a cholesteryl group.

4. The cosmetic product as claimed in claim 1, wherein the proportion of cholesteryl groups introduced by substitution for the hydroxyl groups of the monosaccharide units of the pullulan is 0.05-15 groups per 100 monosaccharide units.

5. The cosmetic product as claimed in claim 1, wherein the proportion of cholesteryl groups introduced by substitution for the hydroxyl groups of the monosaccharide units of the pullulan is 0.1-10 groups per 100 monosaccharide units.

7. The cosmetic product as claimed in claim 1, wherein the content of the pullulan-cholesterol derivative is in the range from 0.001 to 50%, based on the total weight of the cosmetic product.

8. The cosmetic product as claimed in claim 1, wherein the cosmetic product is a skin care cosmetic, make-up cosmetic or hair conditioning cosmetic.

9. The cosmetic product as claimed in claim 1, wherein the cosmetic product is an emulsion, a beauty wash, a rouge, a manicure product or a hair lotion.